UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DR. BERISH RUBIN and DR. SYLVIA L. ANDERSON,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 09-10040-DJC**
THE GENERAL HOSPITAL CORPORATION,	)	
Defendant.	)	

MEMORANDUM AND ORDER

CASPER, J. April 28, 2011

I. Introduction

Plaintiffs Drs. Berish Y. Rubin and Sylvia L. Anderson ("Drs. Rubin and Anderson" or "Plaintiffs") brought this action against The General Hospital Corporation ("MGH" or "Defendant") to correct inventorship of two patents under 35 U.S.C. § 256 and invalidate those patents under 35 U.S.C. 102(f). Defendant moves for summary judgment with respect to the two remaining counts of the complaint on the grounds that the Plaintiffs, who did not engage in any collaborative efforts with the named inventors of the two patents, cannot obtain relief under section 256. For the reasons set forth below, the Court agrees with the Defendant and its motion for summary judgment is GRANTED.

II. Factual Background

The following facts are undisputed unless otherwise noted. The invention claimed in the two patents relate to the discovery of two genetic mutations that are associated with Familial Dysautonomia ("FD"). (Compl. ¶ 10).[1] FD, also known as Riley-Day Syndrome, is an autosomal recessive disorder characterized by developmental arrest in the sensory and autonomic nervous systems and primarily affects the Ashkenazi (Eastern European) Jewish population. (Pl. Opp. Ex. 16, MGH-P000009067). Individuals with FD are affected with a variety of symptoms including decreased sensitivity to pain and temperature, cardiovascular instability, recurrent pneumonias, vomiting crises, and gastrointestinal dysfunction. (Pl. Opp. Ex. 16, MGH-P000009067). No cure exists for FD; approximately one-half of those afflicted die by age thirty. (Def. Memo at 2). Identifying the mutations enables prenatal diagnosis of FD which allows for detection of potential carriers who are at risk for having a child afflicted with the disease. (Def. Memo at 2; Pl. Opp. Ex. 53, RA 00406). Knowledge of the gene associated with FD would also facilitate the development of effective therapeutic approaches for individuals with FD. (Pl. Opp. Ex. 53, RA 00406).

A. Patents-in-Suit

The two patents involved in this case are U.S. Patent Nos. 7,388,093 ("the '093 patent") and No. 7,407,756 ("the '756 patent"). Both patents concern inventions relating to the discovery of two genetic mutations associated with FD, referred to as the major mutation and the minor mutation,

[1]For the purposes of this Memorandum and Order, all references to the parties' filings are abbreviated as follows: Complaint ("Compl."); Defendant's memorandum in support of its motion for summary judgment ("Def. Memo"); Plaintiffs' opposition to Defendant's motion for summary judgment ("Pl. Opp."); documents produced by the Plaintiffs in discovery ("RA####); documents produced by the Defendant in discovery ("MGH#######"); Plaintiffs' response to Defendant's statement of material facts ("Pl. Resp. to Def. Statement of Facts"); and deposition transcripts attached as exhibits to the parties' filings ("[name] Tr.").

respectively:

1. ‘093 Patent

This patent, entitled, “Gene For Identifying Individuals with Familial Dysautonomia,” is directed to “[a] kit for assaying for the presence of a mutation associated with Familial Dysautonomia in an individual comprising primers 18F (SEQ ID NO:82) and 23R (SEQ ID NO:84) that are capable of amplifying a region of IKBKAP of sufficient size to detect a FD1 [major] mutation at position 34,201 of SEQ ID NO:1 or a FD2 [minor] mutation at position 33,714 of SEQ ID NO:1, wherein said region amplified comprises a FD1 [major] mutation at position 34,201 of SEQ ID NO:1 or a FD2 [minor] mutation at position 33,714 of SEQ ID NO:1.” (Compl. Ex. A [‘093 patent, Claim 1]). The remaining claims of the ‘093 patent also concern the major and minor mutations associated with FD. (Compl. Ex. A [‘093 patent, Claims 2-10]).

2. ‘756 Patent

This patent, entitled, “Methods for Detecting Mutations Associated With Familial Dysautonomia,” is directed to “[a] method for assaying for the presence of a mutation associated with Familial Dysautonomia in a human subject, said method comprising detecting the presence of a FD1 [major] mutation wherein the thymine nucleotide at position 34,201 of SEQ ID NO:1 is replaced by a cytosine nucleotide, or a FD2 [minor] mutation wherein the guanine nucleotide at position 33,714 of SEQ ID NO:1 is replaced by a cytosine nucleotide in DNA or RNA from a biological sample from said human.” (Compl. Ex. B [‘756 patent, Claim 1]). The remaining claims of the ‘756 patent also concern the major and minor mutations associated with FD. (Compl. Ex. B [‘756 patent, Claims 2-8]).

B. Events Leading to Patent Issuance

MGH was responsible for the preparation of the '093 and '756 patents before the United States Patent and Trademark Office ("USPTO"). (Compl. ¶ 4). Two MGH employees, Dr. James F. Gusella and Dr. Susan A. Slaugenhaupt ("the MGH scientists"), are the named inventors of the '093 and '756 patents (Compl. ¶¶ 2, 16) and MGH is the record assignee of both patents. (Compl. ¶ 7).

Plaintiffs Drs. Rubin and Anderson are principal investigators in the FD field. (Compl. ¶ 6). At some point in 2000, they claim they discovered that two mutations in the gene encoding a protein called IkB kinase complex-associated protein (IKAP) were responsible for FD and prepared an article entitled, "Familial Dysautonmia Is Caused By Mutations Of the IKAP Gene" (the "article") for publication. (Compl. ¶ 13).

The Plaintiffs and the MGH scientists have never worked together on FD research. There is no suggestion in the record that the Plaintiffs conferred, cooperated, interacted or even consulted with the named inventors. The only connection to the MGH scientists that Plaintiffs rely upon are: the fact that they were aware of the MGH scientists' research on the subject matter; that they considered aspects of the MGH scientists' published work in their own research along with other publications; and that Dr. Gusella reviewed the abstract of Dr. Rubin's article and used it to build upon his own research. (Pl. Opp. at 7-8). On December 20, 2000, Dr. Rubin wrote to Dr. Stephen Warren, the editor of the American Journal of Human Genetics ("Journal"), and attached a manuscript of the article for review and publication, identifying four individuals whom he believed to be qualified to review the manuscript and identifying Drs. Slaugenhaupt and Gusella at MGH as individuals who should not review it. (Compl. ¶ 17; Pl. Opp. Ex. 73). Drs. Rubin and Anderson

already knew that the MGH scientists were working in the FD field at the time. (Compl. ¶ 16). Drs. Rubin and Anderson submitted the article for publication to the Journal on December 21, 2000 and the article was published on January 22, 2001. (Compl. ¶ 13). The article described and identified the major and minor mutations and the region of the IKAP gene where the FD mutations are found. (Compl. ¶¶ 14-15).

On December 22, 2000, Dr. Gusella became aware of an abstract of the article written by the Plaintiffs that had arrived in his office from the Journal for review and acknowledged that upon seeing it, he believed the Plaintiffs had "identified the two mutations that [MGH scientists] had discovered several months earlier and were reported in the paper that we were prepared to submit." (Def. Memo Ex. 21, Gusella Tr. 24:17-24).

Shortly thereafter, on January 6, 2001, Drs. Slaugenhaupt and Gusella filed a patent application claiming inventorship of the'756 and '053 patents (U.S. Serial No. 60/260/080). (Compl. ¶ 16). Drs. Rubin and Anderson allege that Dr. Gusella and his colleagues read the abstract and used the information, then publicly unknown, in the patent application without the knowledge or consent of Dr. Rubin or Dr. Anderson. (Compl. ¶¶ 20-25).[2] At that time, Drs. Rubin and Anderson had filed no patent application and only had a draft patent application dated December 19, 2000. (Pl. Resp. to Def. Statement of Facts ¶ 5). Drs. Rubin and Anderson subsequently filed their own provisional patent application (U.S. Serial No. 60/260, 080) on January 17, 2001. The

[2]In their opposition to Defendant's motion for summary judgment, Plaintiffs include a concise statement of material facts of record as to which they contend there exists a genuine issue to be tried pursuant to Local Rule 56.1 including this allegation that Dr. Gusella received and reviewed the abstract, (Pl. Opp. 12), which is discussed at length at pp. 12 - 13 and 17-19. The other alleged disputed issues of material fact that Plaintiff points to in its opposition concern the alleged dates regarding the priority of invention, which as discussed *infra*, the Court need not address for the purposes of resolving the Defendant's motion.

PTO issued the MGH scientists the '093 patent on June 17, 2008 and the '756 patent on August 5, 2008. (Compl., Exs. A, B).

III. Procedural History

On January 12, 2009, Drs. Rubin and Anderson filed the instant complaint against MGH, seeking complete substitution of inventors pursuant to 35 U.S.C. § 256 (Count I), to be added as co-inventors also under 35 U.S.C. § 256 (Count II) and to invalidate the two patents under 35 U.S.C. § 102(f) (Count III). (Docket #1). On November 22, 2010, the Court (Saris, J.) adopted Magistrate Judge Robert Collings' report and recommendation and dismissed Count III as duplicative of the other counts.

MGH has now moved for summary judgment on the remaining two counts under Fed. R. Civ. P. 56. This matter was transferred to this session on January 27, 2011 and the Court heard oral argument on March 15, 2011. Because a suit for the correction of inventorship of an issued patent arises under 35 U.S.C. § 256 and hence the patent laws, the Court has jurisdiction under 28 U.S.C. § 1338(a).

IV. Discussion

Summary judgment is appropriate if there is no genuine dispute as to any material fact and the undisputed facts show that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). "An issue is genuine if the evidence of record permits a rational factfinder to resolve it in favor of either party." Borges ex. rel. S.M.B.W. v. Serrano-Isern, 605 F.3d 1, 4 (1st Cir. 2010) (internal quotation marks and citations omitted). "A fact is material if its existence or nonexistence has the potential to change the outcome of the suit." Id. at 5. The moving party bears the burden of showing the district court the basis for

its motion and identifying where there exists a lack of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

"Once the moving party has accomplished this feat, the burden shifts to the nonmoving party, who must, with respect to each issue on which she would bear the burden of proof at trial, to demonstrate that a trier of fact could reasonably resolve that issue in the her favor." Borges, 605 F.3d at 5 (citing Celotex, 477 U.S. at 324). "If the nonmovant fails to make this showing, then summary judgment is appropriate." Id. The Court must view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. Barbour v. Dynamics Research Corp., 63 F.3d 32, 37 (1st Cir. 1995) (citing Woods v. Friction Materials, Inc., 30 F.3d 255, 259 (1st Cir. 1994). However, disputes over facts that are not material to the issues raised will not defeat a motion for summary judgment. Anderson, 477 U.S. at 247-48.

A. Scope and Purpose of 28 U.S.C. § 256 –"Correction of Named Inventor"

Named inventors on an issued patent are presumed to be the true and only inventors. Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998) (citing Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997), cert. denied, 520 U.S. 1277 (1997)). Section 256, the statutory provision upon which Plaintiffs brings Counts I and II, permits correction of the named inventors on a patent. 35 U.S.C. § 256; Pannu v. Iolab Corp., 155 F.3d 1344, 1350 (Fed. Cir. 1998); MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568, 1570 (Fed. Cir. 1989). Section 256, titled "Correction of named inventor," states:

> Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate

> correcting such error.
>
> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

35 U.S.C. § 256. This provision, enacted in 1952, is remedial in nature. Prior to its enactment, if an inventor was erroneously named or excluded in an issued patent, the only mechanism to correct the error was to invalidate the patent. See, e.g., Pannu, 155 F.3d at 1350. Section 256 has been characterized by the Federal Circuit as a "savings provision"; it allows the correction of the patent instead of automatic invalidation. Id. That is, as originally enacted, the statute "permits a bona fide mistake in joining a person as [an] inventor or in failing to join a person as an inventor to be corrected." S. Rep. No. 82-1979, at 7-8 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2401-02; see S. Rep. No. 82-1979, at 27 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2421 (noting that "[t]his section is new and a companion to section 116"). Section 116, together with section 256 with which it should be read, was added in 1952 "for the purpose of removing technical grounds for attacking the validity of patents by reason of the erroneous naming of inventors." Patterson v. Hauck, 52 C.C.P.A. 987, 997 (1965).

In 1982, section 256 and its companion, section 116 were amended. Section 116 was amended to "enlarge the possibilities for correction of misnamed inventors in issued patents." H.R. Rep. No. 97-542, 97th Cong., 2d Sess. 10 (1982), reprinted in 1982 U.S.C.C.A.N. 765, 774. Such possibilities include "cases where the person originally named as inventor was not in fact the inventor of the subject matter contained in the application." Id. at 773. Congress made clear that

"[s]ection 256 . . . [as] a companion to section 116, would be amended to similarly enlarge the possibilities for correction of misnamed inventors in issued patents." Id. at 774.[3]

Even in light of the 1982 amendment, the purpose of section 256 remains the same; that is, to correct "a bona fide mistake in inventorship . . . without precluding its application in instances of deliberate nonjoinder of an inventor," Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1554 (Fed. Cir. 1997) ("Stark II") (internal citations and quotation marks omitted). Accordingly, section 256 provides a mechanism to correct two types of inventorship errors: misjoinder and nonjoinder. Fina Tech., Inc., v. Ewen, 265 F.3d 1325, 1328 (Fed. Cir. 2001); Stark II, 119 F.3d at 1553. Misjoinder occurs when a person who is not an inventor is mistakenly listed as an inventor. Stark II, 119 F.3d at 1553. Section 256 allows for deletion of a misjoined inventor "whether that error occurred by deception or by innocent mistake." Id. at 1555. Nonjoinder occurs when a person who is an inventor mistakenly has not been listed as such where "the error [does not] involve any

[3]Pub. L. 97-247, § 6(b), substituted "Correction of named inventor" for "Misjoinder of inventor" as the section's title, and, in text, substituted "Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error" for "Whenever a patent is issued on the application of persons as joint inventors and it appears that one of such persons was not in fact a joint inventor, and that he was included as a joint inventor by error and without any deceptive intention, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate deleting the name of the erroneously joined person from the patent," substituted "The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred it if can be corrected as provided in this section" for "Whenever a patent is issued and it appears that a person was a joint inventor, but was omitted by error and without deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate adding his name to the patent as a joint inventor," and struck the provision that the misjoinder or nonjoinder of joint inventors not invalidate a patent, if such error can be corrected as provided in this section.

deceptive intention by the nonjoined inventor." Id. at 1553. "If a patentee demonstrates that inventorship can be corrected as provided for in section 256, a district court must order correction of the patent, thus saving it from being rendered invalid." Pannu, 155 F.3d at 1350.

Defendant now seeks summary judgment on both Counts I and II on the grounds that Plaintiffs "cannot invoke Section 256 because they do not meet its threshold requirements of being joint inventors." (Def. Memo at 16). The Court shall address Defendant's motion as to each count, beginning with Count II in which the Plaintiffs seek to be added to the two patents as co-inventors under section 256.

1. Adding Plaintiffs as Co-Inventors

In Count II of the Complaint, the Plaintiffs allege that they "conceived subject matter described and claimed in [the] '093 and '756 patents, " and are "co-inventors of the invention described and claimed in '093 and '756 patents." (Compl. ¶¶ 33-34). Since Plaintiffs are seeking to be added as joint inventors the Court looks to section 116 which sets forth the requirements for joint inventorship and is the companion to section 256. Stark II, 119 F.3d at 1555. Section 116 states:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.
> . . .
> Whenever through error a person is named in an application for patent as the inventor, or through error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as

he prescribes.

For persons to be joint inventors under section 116, "there must be some element of joint behavior such as collaboration or working under common direction." Kimberly-Clark Corp. v. Procter & Gamble Co., 973 F.2d 911, 916-17 (Fed. Cir. 1992).[4] There must be "*collaboration* of the inventive endeavors of two or more persons *working toward the same end* and producing an invention by their *aggregate* efforts." PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 12 F. Supp. 2d 69, 84 -85 (D. Mass. 1998) (citing Kimberly-Clark, 973 F.2d at 916) (emphasis in original); see Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997) (although Section 116 "sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor," a joint invention is a "a product of a collaboration between two or more persons working together to solve the problem addressed") (citation omitted).[5] Individuals cannot be joint inventors if they are totally independent of each other. Kimberly-Clark, 973 F.2d at 917.

A. Plaintiffs Did Not Collaborate with the MGH Scientists

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[4]In Kimberly-Clark, 973 F.2d at 916-17, the Federal Circuit confirmed that an invention can be made "jointly" under section 116 only if two or more persons actually collaborate in it. As the Federal Circuit noted, the purpose of the amendment was to encourage team research. Id. In determining co-inventorship, courts look to a number of factors, the most important being the relationship of the scientists who conceived the idea and who reduced it to practice. See Celestron Pacific v. Criterion Mfg., 552 F.Supp. 612, 616 n. 1 (D. Conn. 1982).

[5]Commentators agree. See 3 Moy's Walker on Patents § 10.24 (4th ed.) ("[T]wo persons are considered to have made an invention jointly if they worked on the invention collaboratively and each contributed to the invention being conceived"); 3 Pat. L. Fundamentals § 17.4 (2d ed.) ("Joint invention connotes *collaboration* of effort to produce a complete and operative invention. Persons are joint inventors when they work together to solve a particular problem").

Drs. Rubin and Anderson argue that they collaborated with the MGH scientists and are therefore joint inventors because they were aware of the MGH scientists' research on the subject matter, considered aspects of the MGH scientists' published work in their own research along with other publications,[6] and because when Dr. Warren transmitted Dr. Rubin's abstract[7] in December 2000, Dr. Gusella reviewed it and used it to build upon his own research. At oral argument, counsel for Drs. Rubin and Anderson argued that the transmission of the abstract, standing alone, amounts to collaboration. Specifically, counsel argued that Drs. Rubin and Anderson identified the mutations claimed in the two patents in the abstract inadvertently transmitted to Dr. Gusella and that Dr. Gusella was able to identify the mutations only after he reviewed Dr. Rubin's abstract which then allowed the MGH scientists to complete and file their patent application.

Even viewing all of these facts in the light most favorable to the Plaintiffs, it still cannot be said that Drs. Rubin and Anderson collaborated with the MGH scientists. Although there is no bright line standard to determine whether a person is a joint inventor, see Fina Oil, 123 F.3d at 1473,

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[6]One of the Plaintiffs' technical assistants, Rocco Coli, testified that at the direction of Plaintiffs, he utilized certain genetic markers that the MGH scientists had published in the Journal to narrow the scope of the search for the mutations. (Pl. Opp. Ex. 3, Coli Tr., 35:24-36:4). By using the markers identified in the MGH scientists' work, Mr. Coli was able to build a genetic map and assisted Plaintiffs in localizing the gene containing the mutations responsible for causing FD.

[7]There is some dispute as to whether Dr. Gusella reviewed the manuscript or abstract of Plaintiffs' article. Defendants claim Dr. Gusella received the abstract only. (Def. Memo at 9, 10). In their complaint, Plaintiffs allege that Dr. Warren sent Dr. Gusella the "manuscript or a summary" of Plaintiffs' article. (Compl. ¶ 20, 22). In their opposition to Defendant's motion for summary judgment, Plaintiffs argue that "at least an abstract" of the article was sent to Dr. Gusella. (Pl. Opp. at 1, 8) and do not point to any evidence, other than Dr. Gusella's deposition and Dr. Warren's deposition regarding the transmittal of the abstract, to suggest otherwise. (Pl. Opp. at 12). This distinction does not rise to the level of genuine issue of material fact, since even assuming *arguendo* that Dr. Gusella did in fact receive the manuscript, the result here would be the same.

the Federal Circuit has made clear that "his labors must be conjoined with the efforts of the named inventor because joint inventorship . . . can only arise when collaboration or concerted effort occurs - that is, when the inventors have the same open line of communication during or in temporal proximity to their inventive efforts." Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004); see Ethicon, 135 F.3d at 1459 (finding joint inventorship where unnamed inventor alleged he contributed certain features of a patented surgical instrument while collaborating with the named inventor for approximately eighteen months); PerSeptive, 12 F.Supp.2d at 85 (finding joint inventorship where unnamed and named inventors conducted research together, shared research results, and shared ideas related to the patent). Even if it is true under section 116 that inventors need not physically work together or at the same time, that each inventor need not make the same type or amount of contribution and each need not make a contribution to the subject matter of every claim, it is clear on the record that Drs. Rubin and Anderson had no contact with the MGH scientists much less worked together in any capacity to identify the mutations related to the two patents.

Moreover, in filing their own provisional patent application on January 17, 2001 and subsequent patent applications that claim priority to their provisional application, U.S. Serial No. 10/050,189 (filed Jan. 16, 2002; abandoned) and 12/339,581 (filed Dec. 19, 2008; pending), Plaintiffs did not name the MGH scientists as co-inventors, which evidences the fact that plaintiffs must not have considered themselves to be collaborating with the MGH scientists. (Def. Memo, Ex. 16 (Plaintiffs' provisional patent application)). Their lack of collaboration is further confirmed by Plaintiffs' own testimony that they had not collaborated with Drs. Gusella and Slaugenhaupt (Def. Memo Ex. 13, Anderson Tr., 52:20-24; Def. Memo Ex. 12, Rubin Tr., 147:7-9) and Plaintiffs' admission that they used publicly available information to narrow the location of the FD gene, used

"different research techniques" and "were able to achieve their discovery of the mutations over a period of several months" (Pl. Resp. to Def. Statement of Facts ¶ 7) - an alleged discovery made independent from the MGH scientists. Drs. Rubin and Anderson cite no authority where such unknowing and unwitting collaboration amounts to joint inventorship without providing some evidence of joint behavior.

Drs. Rubin and Anderson's reliance on Kimberly-Clark, 973 F.2d at 917, to support their argument that the transmission of the abstract to Dr. Gusella is sufficient to constitute joint inventorship is misplaced. Kimberly-Clark does not stand for the proposition that building upon a relevant report on its own rises to the level of collaboration, because as the Federal Circuit stated, "joint behavior" is required. 973 F.2d at 917. The Federal Circuit explained that "the language and legislative history of Section 116 make clear that *collaboration is required* . . . What is clear is that the statutory work 'jointly' is not mere surplusage. For persons to be joint inventors under Section 116, there must be some element of joint behavior, such as *collaboration* or *working under common direction*, one inventor seeing a relevant report and building upon it or hearing another's suggestion as a meeting...." Id. (emphasis added). Thus, joint inventorship requires "joint behavior" between two parties or some element of working together on the subject matter which is noticeably absent in this case.

Drs. Rubin and Anderson's reliance on Memry Corp. v. Ky. Oil Tech., No. C-04-03843 RMW, 2007 U.S. Dist. LEXIS 73315, at *33-37 (N.D. Cal. Sept. 20 2007) is equally unavailing. In that case, the court found the evidence could reasonably suggest collaboration and thus joint inventorship where a third party discussed the named inventor's project with the unnamed inventor before the patent applications were even drafted, the third party participated in design meetings with

the named inventor, and the third party communicated with the named inventor throughout the project. Id. at 35-37. The named and unnamed inventors were also more than aware of each other. Id. Here, there is no evidence of even sporadic communication or interaction between the Editor of the Journal and either Drs. Rubin and Anderson or the MGH scientists from which the Court could reasonably infer that Drs. Rubin and Anderson "collaborat[ed] and work[ed] together [with the MGH scientists even through Dr. Warren] to collectively have a definite and permanent idea of the complete invention." Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297, 1308 (Fed. Cir. 2010); see also Falana v. Kent State Univ., No. 5:08 CV 720, 2010 WL 5178838, at *15-16 (N.D. Ohio Dec. 15, 2010) (finding unnamed inventor was a co-inventor because in making his contribution to the conception of the invention, he collaborated with the named inventors on the patent the entire time he worked on the project and the named inventors themselves described the project as "collaborative" and a "team effort"). Accordingly, the Court declines to interpret the meaning of collaboration to include unknowing collaboration and expand the reach of 35 U.S.C. §§ 116 and 256 in the manner espoused by Plaintiffs.

To rule otherwise would mean that any independent researcher could bring suit under section 256 claiming they were the first to invent the patented subject matter. This would defeat the very purpose of not only determining priority of invention under 35 U.S.C. § 135 and the interference proceedings before the USPTO, discussed *infra*, but of section 256 itself. Section 256 is not a mechanism to determine who among independent researchers was the first to invent; rather it is a "savings provision" to prevent patent rights from being extinguished simply because the inventors are not correctly listed. Pannu, 155 F.3d at 1349-50. It is in the interest of both inventors and the public that mistakes in naming inventors who worked jointly on a particular subject matter can be

corrected under section 256. Drs. Rubin and Anderson do not seek to correct a mistake; they seek to invoke section 256 to obtain a declaration that they were the first to invent, which appears beyond the statute's intended purpose.

B. Plaintiffs Have Failed to Prove Joint Inventorship by Clear and Convincing Evidence

Even if section 256 was the correct vehicle for the challenge Plaintiffs now bring, Plaintiffs still could not prove by clear and convincing evidence that they are joint inventors. A person seeking to add his name as a co-inventor "must meet the heavy burden of proving [their co-inventorship] by clear and convincing evidence." Shum v. Intel Corp., 633 F.3d 1067, 1083 (Fed. Cir. 2010) (quoting Eli Lilly, 376 F.3d at 1358). To meet this burden, the alleged co-inventors must prove their contribution to the conception of the invention with more than their own testimony concerning the relevant facts. Gemstar-TV Guide Int'l, Inc., v. Int'l Trade Comm'n, 383 F.3d 1352, 1382 (Fed. Cir. 2004) (citations omitted). Whether the proffered evidence sufficiently corroborates the alleged inventor's testimony is evaluated under a "rule of reason" analysis. Price v. Symsek, 988 F.2d 1187, 1195 (Fed. Cir. 1993). Under this analysis, "[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the [alleged] inventor's story may be reached." Id.

"Corroborating evidence may take many forms." Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1327 (Fed. Cir. 2004). "Reliable evidence of corroboration preferably comes in the form of records made contemporaneously with the inventive process." Id. (citing Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350-51 (Fed. Cir. 2001)). "Circumstantial evidence of an independent nature about the inventive process" and "oral testimony from someone other than the alleged inventor" may also corroborate. Trovan, Ltd. v. Sokymat SA, Irori, 299 F.3d

1292, 1303 (Fed. Cir. 2002). An alleged co-inventor's testimony, standing alone, cannot rise to the level of clear and convincing evidence. Ethicon, 135 F.3d at 1461. When evidence, viewed in a light most favorable to the non-moving party, fails to establish the inventorship of an omitted inventor by clear and convincing evidence, summary judgment is appropriate. Linear Tech Corp., 379 F.3d at 1327.

Here, Plaintiffs have failed to show by clear and convincing evidence that they contributed to the identification of the mutations claimed in the patents at issue to qualify as joint inventors. Plaintiffs argue that they contributed to MGH scientists' identification of the mutations claimed in the two patents by the transmission of the abstract to Dr. Gusella which allowed the MGH scientists to finally identify the mutations which Plaintiffs allege the MGH scientists had not yet discovered. Plaintiffs claim that after the Plaintiffs' team discovered the major FD mutation in September 2000 and the minor mutation in early October 2000 by DNA sequence analysis, they spent several weeks characterizing the pathogenic nature of the mutations: for the major mutation, the technique of Western blot analysis was used to show that a defective protein was made because of the alternative splicing and for the minor mutation, radiolabeling and immunoprecipitation showed that the minor mutation caused defective phosphorylation of the IKAP protein. (Pl. Opp. at 9). Plaintiffs claim by late November 2000, they had submitted a manuscript of the article disclosing the discovery of the two mutations to the Journal. (Pl. Opp. at 10).

Plaintiffs argue that the MGH scientists discovered the mutations only after Dr. Gusella reviewed the abstract of the article which allowed the MGH scientists to recognize which mutations caused FD. (Pl. Opp. at 10). Plaintiffs rely on its expert's statement in its expert report that "the [i]dentity of the major mutation is explicitly stated in the third sentence of the Abstract: 'Sequence

analysis reveals a T-C transition in the donor splice site of intron 20.' Thus, the second sentence of the abstract was sufficient to disclose the exact position and nature (T-C) of this, the major FD mutation." (Pl. Opp. at 11, Oppenheim Report at 16). Dr. Oppenheim also states in her report that the fourth sentence in the abstract discloses the minor mutation to a skilled person. (Pl. Opp. at 11, Oppenheim Report at 16).

Plaintiffs also point to Dr. Gusella's testimony that he read and understood the abstract of Plaintiffs' article as identifying "the two mutations that [MGH scientists] had discovered several months earlier and were reported in the paper that we were prepared to submit." (Pl's Resp. to Def. Statement of Facts ¶¶ 3-4; Pl. Opp. Ex. 21, Gusella Tr. 24:17-24). Plaintiffs direct the Court to an email Dr. Gusella sent to Dr. Warren, the Editor of the Journal, in which Dr. Gusella states:

> "As you may know, Sue Slaugenhaupt and I have been working on [FD] for several years. We have recently identified the major and minor FD mutations and have written a paper that we were planning to submit to another joint next week. Although I have only seen the abstract of the fasttrack short report (00-2572), I believe that our competitors have identified the same two mutations. However, we have data that indicates that the situation is more complicated than a simple inactivation and in fact shows tissue-specific expression of a major splicing alteration. Obviously, we are in a predicament. Needless to say, I can't review the paper that I was asked to, but I also don't want to get into a competition of seeing which journal can publish more quickly....."

(Pl. Opp. Ex. 32, MGH-P000011098). Plaintiffs also point to the fact that despite not realizing Dr. Gusella's research had progressed to the stage of identifying the two mutations, Dr. Warren provided Dr. Gusella with the abstract regarding the Plaintiffs' identification of the mutations. (Pl. Resp. to Def. Statement of Facts ¶¶ 3-4; Pl. Opp. Ex. 1, Warren Tr. 142:22-143:2). However, Dr. Warren discussed this information with Dr. Gusella after Dr. Gusella had received Plaintiffs' abstract. (Pl.

Opp. Ex. 1, Warren Tr. 139:1-143:2; MGH-P000011098). Dr. Gusella's testimony and his email to Dr. Warren explaining that he believed Plaintiffs had identified the same mutations that he and Dr. Slaugenhaupt had already discovered does not show by clear and convincing evidence that Plaintiffs contributed to the MGH scientists' identification of the mutations with the transmission of the abstract. It suggests the opposite; that is, that the MGH scientists discovered the mutations and Dr. Gusella discussed the abstract with Dr. Warren only after that discovery. Plaintiffs present no evidence that they communicated their conception of the identification of the mutations as being responsible for the FD gene with the MGH scientists during the Plaintiffs' or MGH scientists' research.[8] Accordingly, in viewing the facts in the light most favorable to the Plaintiffs in this case, the Court finds that there is no clear and convincing evidence from which any rational trier of fact could conclude that Plaintiffs have proven that they are co-inventors of the patents at issue. As there is no genuine issue of material fact for trial, Defendants are entitled to summary judgment as a matter of law on Count II.

2. Complete Substitution Under 28 U.S.C. § 256

Under Count I, the Plaintiffs seek complete substitution as inventors under Section 256, alleging that they "were the first persons to conceive the subject matter described and claimed in the '093 and '756 patents" and "are the true and only co-inventors of the inventions described and claimed in the '093 and '756 patents" and, "should be substituted for the two presently named inventors" or "should be added to the two presently named inventors." (Compl. ¶¶ 27-30). By its very nature, Count I rests on the Plaintiffs' contention that they were the first and sole inventors of

[8]As discussed *supra*, Plaintiffs' co-inventorship claim is further belied by their own admission that they did not collaborate with the MGH scientists to discover the mutations. See pp. 13.

the subject matter claimed in the patents. This claim concerns priority of invention. As the Defendant argues and as discussed above, section 256 is not intended to resolve disputes concerning priority of invention but is intended to encourage collaboration between and among inventors and correct the named inventors without the need to invalidate the patent. (Def. Memo 14); see Pannu, 155 F.3d at 1349-50; Stark II, 119 F.3d at 1554.

At oral argument, counsel for the Plaintiffs argued that "tens of cases" have allowed complete substitution for inventors in cases such as this one. However, with the exception of one district court case, Yeda Research & Dev. Co. v. Imelone Sys., Inc., 443 F. Supp. 2d 570 (S.D.N.Y. 2006) discussed below, the only cases that the Plaintiffs cited to the court in their papers or at oral argument that allowed complete substitution were cases where the unnamed and named inventor had collaborated. In the leading case cited by the Plaintiffs, Stark II, the plaintiff collaborated with the defendant in developing certain magnetic resonance imaging (MRI) technologies which resulted in six patents. 119 F.3d at 1552; see Stark v. Advanced Magnetics, Inc., 29 F.3d 1570, 1572 (Fed. Cir. 1994) ("Stark I"). The plaintiff filed suit for correction of inventorship under section 256 alleging he was the sole inventor of the subject matter covered by one of the six patents and the joint inventor of the remaining five patents. Stark II, 119 F.3d at 1552. Defendants had failed to name plaintiff as a co-inventor on any of the six patents, Id., despite the fact that an annual report referred to defendant's "collaboration with Dr. Stark." Stark I, 29 F.3d at 1572. The issue in Stark was whether section 256 requires both named and unnamed inventors act without deceptive intent. Stark II, 119 F.3d at 1554-55. The Court held that "Section 256 merely precludes deceptive intention in the inventor that seeks to be restored to a rightful place in the patent." Id. at 1556. On this basis, with respect to one specific patent on which defendant stated it had collaborated with Dr. Stark in

an annual report, the Court found that "Section 256 allows complete substitution of inventors so long as the true inventors are without deceptive intent." Id. Thus, substitution under section 256 was permissible only because the plaintiff and defendants had worked together yet defendant completely omitted plaintiff's name from the patent applications.

The plaintiffs cite to a number of courts that have followed Stark II and those courts have also found substitution permissible where the parties collaborated or worked together on the subject matter claimed in the patent. See Virginia Elec. & Lighting Corp. v. Nat'l Serv. Indus. Inc., No. 99-1226, 2000 U.S. App. LEXIS 131, at *2-6 (Fed. Cir. Jan. 6, 2000) (substitution permissible where plaintiff signed agreements with the named inventor's employer and provided it with product development and manufacturing assistance, as well as prototypes yet plaintiff was omitted from the patent application); J&J Mfg., Inc., v. Logan, 24 F. Supp. 2d 692, 694-94, 698 (E.D. Tex. 1998) (denying motion to dismiss in an action under section 256 for substitution where named inventor initiated a relationship with putative inventor's employer and over time, purchased products from it, received documentation regarding one particular device developed only by putative inventors and named inventor was granted a patent for precisely that product while omitting the putative inventors from the patent application).[9]

The Court acknowledges that one of the cases upon which Plaintiffs rely, Yeda, 443 F. Supp. 2d 570, stands in a different posture than the cases discussed above since the court in that case found no collaboration, but it still is of little aid to their argument. In Yeda, the named inventors had

[9]Plaintiffs' reliance on Chou v. University of Chicago, 254 F.3d 1347 (Fed. Cir. 2001) is misplaced. In Chou, the plaintiff was not named on any patents but conducted research and co-authored articles with the named inventor. Id. at 1353-54. Unlike the plaintiff in Chou, Plaintiffs here seek to be added as co-inventors or substituted despite a lack of collaboration between them and the MGH scientists.

conducted no research concerning the patent at issue and only provided an antibody sample that plaintiffs used in their research. Id. at 594, 597. Plaintiffs and one named inventor discussed the research related to the patent at issue - research conducted *only* by plaintiffs. Id. at 601-604. Two of the named inventors were listed as co-authors of several papers revealing the plaintiff's discovery even though they had not discussed any research results with the plaintiffs prior to the named inventors sharing drafts with them. Id. Despite having conducted no independent research prior to receiving the results of the plaintiffs' research, the named inventors filed a patent application to claim they conceived of the invention and reduced it to practice. Id. at 603-605. On that basis, the Court held that substitution was permissible. Id. at 615, 618-623. The Court made clear, however, that the fact that the named inventors shared a sample with plaintiffs for their research did not amount to joint inventorship and found "no creditable evidence suggesting that the named inventors ever made any suggestions to the [unnamed] scientists during their research or in any other way influenced the course of their experiments." Id. at 620-21, 623. In stark contrast to the parties in Yeda, here, not only is there is no relationship between the MGH scientists and the Plaintiffs, but both parties conducted their own research to identify the minor and major mutations associated with FD - research conducted over a period of time independent of one another.

Other district courts have not allowed substitution under section 256 where the parties have not collaborated on the subject matter of the patents at issue. See e.g., Maxwell v. Stanley Works, No. 3:06-0201, 2006 WL 1967012, at *2, 4-5 (M.D. Tenn. July 11, 2006) (substitution impermissible where plaintiff claimed he was the original inventor of a wrench after a patent was issued to defendant for the same wrench and plaintiff and named inventor neither communicated nor collaborated with one another); Rawlplug Co., Inc. V. Hilti Aktiengesellschaft, 777 F. Supp. 240,

242-43 (S.D.N.Y. 1991) (substitution impermissible where plaintiff claimed to be the sole and original inventor of a device later patented by another company with whom plaintiff had no contact but plaintiff alleges received the information concerning the device from plaintiff's former employee). For the reasons discussed *supra*, the Court finds that the Plaintiffs and the MGH scientists did not collaborate for the purposes of joint inventorship on the subject matter claimed in the patents at issue. If the purpose of Section 256 is to "encourage joint inventorship," Ethicon, Inc. v. U.S. Surgical Corp., 954 F. Supp. 51, 54 (D. Conn. 1997), aff'd 135 F.3d 1456 (Fed. Cir. 1998), even to the extent that it allows correction of patents, post-Stark II, where the named inventors intentionally omitted the true inventors, that same purpose is not served when alleged inventors such as Plaintiffs in this case, seek to be completely substituted under Section 256, where they engaged in separate inventive efforts from the named inventor and had not even the most minimal relationship or interaction with the named inventors. As there is no genuine issue of material fact for trial, Defendants are entitled to summary judgment as a matter of law on Count I.

However, this ruling does not necessarily leave the Plaintiffs without a remedy for its claim. Drs. Rubin and Anderson may challenge priority of invention by initiating interference proceedings under 35 U.S.C. § 135,[10] an administrative proceeding which the Board of Patent Appeals conducts to determine questions of priority, i.e., who was the first to invent the common subject matter

[10]Section 135(a) states that when an "application is made for a patent, which in the opinion of the director, would interference with . . . any unexpired patent, an interference may be declared and the Director shall give notice of such declaration to the . . . applicant and patentee...." 35 U.S.C. § 135(a). Section 135(a) grants the Board of Patent Appeals and Interferences the authority to "determine questions of priority of the inventions and . . . questions of patentability." Id. The statute further states that "A final judgment adverse to a patentee from which no appeal or other review has been or can be taken or had shall constitute cancellation of the claims involved in the patent...." Id.

claimed in one application and an issued patent. 35 U.S.C. § 135; Beech v. Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248-49 (Fed. Cir. 1993). The interference proceeding implements the principle of United States patent law that "the patent right is granted to the first inventor rather than the first to file a patent application." Paulik v. Rizkalla, 760 F.2d 1270, 1272 (Fed. Cir. 1985). At oral argument, the parties agreed that Drs. Rubin and Anderson would not be time-barred if they now choose to proceed with an interference.[11] In an interference proceeding, the parties are allotted time for discovery and testimony of witnesses and there is a final hearing before the Board of Patent Appeals and Interferences. See 37 C.F.R. §§ 1.651, 1.653, 1.654, 1.677, 1.687.[12] After the final hearing, the Board issues a final decision. See 37 C.F.R. § 1.658. Thus, although the Court declines to grant Plaintiffs the relief they seek under section 256 for the aforementioned reasons, it appears that Drs. Rubin and Anderson may pursue relief by initiating an interference under section 135.

V. Conclusion

For the aforementioned reasons, summary judgment in favor of MGH on Counts I and II is GRANTED.

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[11]It appears that the patent examiner on Plaintiffs' patent application (U.S. Serial No. 10/050,189; abandoned in favor of Plaintiffs' currently pending application) advised Plaintiffs on four separate occasions to pursue an interference against the MGH scientists' then-pending patent applications, but Plaintiffs chose not to do so. See MGH-P000007356, MGH-P000007376, MGH-P000007382-84, MGH-P000007406-08 (attached to Def. Reply in Ex. 4).

[12]The Court notes that the protective order entered in this case (Docket #27) states that "the parties may use the discovery material exchanged between them in a subsequent interference proceeding in the U.S. Patent and Trademark Office." (Protective Order ¶ 16). Thus, it cannot be said that initiating an interference in this case would pose any limitations with respect to discovery on Plaintiffs since discovery has been completed in this case and Plaintiffs may use all discovery materials in an interference proceeding.

So ordered.

/s/ Denise J. Casper
United States District Judge